REMARKS

The Office Action mailed July 15, 2003, has been received and reviewed. Claims 1-11, 13-16, 18 and 22-25 are currently pending. New claims 26-30 have been added. Claims 7, 15, 16, and 22 stand objected to because of formalities. Claims 1, 2, 7 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 1-11, 13-16, 18 and 22-25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by either Glabe *et al.* (U.S. Patent 4,178,370) or Goff *et al.* Reconsideration is respectfully requested.

Support for New Claims:

Support for new claim 26 can be found throughout the specification, for example, at page 6, lines 15-23 and original claim 1.

Support for new claims 27-30 can be found throughout the specification, for example, from page 3, line 12 to page 5, line 3.

Objection to the Specification:

The specification is amended to present a "Brief Description of the Drawings," as suggested by the Examiner.

Claim Objections:

Claims 7, 15, 16, and 22 stand objected to because of asserted grammatical errors. Claims 7, 15, 16, and 22 have been amended as suggested by the Examiner. Reconsideration and withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph:

Claims 1, 2, 7 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claim 1 has been amended to remove poultry or pigs. Thus, claims 2 and 7 now refer to "the animal" of claim 1. Claim 2 was also asserted to be confusing, the

applicants have amended this claim as suggested by the Examiner. Claim 22 was rejected[1] as allegedly lacking an essential step. The applicants have amended claim 22 as suggested by the Examiner. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b):

Claims 1-11, 13-16, 18 and 22-25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by either Glabe *et al.* (U.S. Patent 4,178,370) or Goff *et al*, because the soy meal fed to the pigs was thought to have inherently performed the claimed methods according to claims 1-7, 18 and 22-25 and inherently anticipated claims 8-11.

One of the most recent and stringent cases regarding inherency and anticipation is *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003). As noted in *Schering*, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Id.* 339 F.3d at 1377 (emphasis added) (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). Thus, for a reference to inherently disclose a feature, the reference must necessarily produce that feature. For example, in *Schering* the court found that "[t]he record shows that DCL necessarily and inevitably forms from loratadine under normal conditions" *Id.* 339 F.3d at 1378 (emphasis added).

In addition, for inherency to apply against the method claims, such as claims 1-11 and 18-30, the feed disclosed in the cited reference must necessarily perform the presently claimed induction of calcitriol synthesis when that feed is used "in its normal and usual operation," *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136 (Fed. Cir. 1986) (citations omitted). Therefore, the cited references in their normal and usual operation, feeding of soy or corn-soy meal to an animal, must inherently (necessarily) perform the function of inducing calcitriol synthesis. The cited references, however, do not necessarily and inevitably induce calcitriol synthesis when the feed disclosed therein is fed to an animal.

[1] The applicants note that the list of claims rejected appears to have a typographical omission of claim 22.

Glabe *et al.* does not necessarily and inevitably induce calcitriol synthesis in pigs fed a mixed feed containing soybean meal. In fact, Glabe *et al.* merely discloses feeding soybean meal, which lacks sufficient activity to induce calcitriol synthesis in animals. In general, the content of plasma calcitriol elevating compounds in whole plants, or even whole seeds, is too low to raise plasma calcitriol levels sufficiently (*see* page 4, lines 10-13 of the specification; *see also* page 4, lines 29-33 of the specification).

Likewise, Goff *et al.* (1995) does not disclose feeding a sufficient amount substances (such as, isoflavones, lignans, coumestrol, resorcylic acid lactones and mixtures thereof) to induce, raise above normal levels, calcitriol synthesis. For example, Goff *et al.* (1995) shows that the amount of soybean meal administered by the authors did not induce calcitriol synthesis, as the chickens receiving the feed (the control group) became rachitic (having to do with rickets and vitamin D deficiency). Furthermore, Goff *et al.*, as shown by the $1,25(OH)_2D_3$ levels, did not induce calcitriol synthesis above normal, by supplementing the purified diet with cholecalciferol (Goff *et al.* at p. 1353, second column) or by supplementing the corn-soybean meal with cholecalciferol (Goff *et al.* at the last paragraph spanning pages 1356-1357; and FIG. 1). Therefore, non of the compositions in Goff *et al.* induced calcitriol synthesis, as that term is used in the present claims.

Thus, as can be seen from the references and specification, soy meal does not necessarily and inevitably induce calcitriol synthesis and, therefore, is not inherent in any soy (or any other plant) based feed. *See, e.g.*, Goff *et al.* demonstrating the failure to induce calcitriol synthesis with corn-soybean based feed, with or without additional cholecalciferol.

Finally, the applicants note that increasing immune competence and/or phytate degradation capacity by raising calcitriol levels, as disclosed in the present application and claimed in claims 1-11 and 18, is an unexpected effect. Therefore, raising the calcitriol levels to increase immune competence and/or phytate degradation capacity is a novel and nonobvious finding.

Claims 1-11 and 18-30 are method claims reciting "inducing calcitriol synthesis," which is not taught, expressly or inherently, or suggested by the cited references. Claims 8-21 are

composition claims which recite an amount sufficient to increase calcitriol synthesis, which is not taught or suggested by the cited references. The cited references do not, expressly or inherently, teach or suggest such a method or amount.

In particular, new claims 27-29 are directed to a method of preparing an animal feed having a sufficient amount of a compound to induce calcitriol synthesis in an animal. The cited references do not teach or suggest, either alone or in combination, fractionating a plant or plant part, selecting a fraction enriched for a compound selected from the group consisting of isoflavones, lignans, coumestrol, resorcylic acid lactones and mixtures thereof, and adding a sufficient amount of the fraction to animal feed to induce calcitriol synthesis in an animal when the animal is fed a normal amount of said animal feed. Glabe *et al.* and Goff *et al.*, either individually or in combination, do not teach or suggest fractionating a plant or plant part, selecting a fraction enriched for a compound of the claim and adding a sufficient amount of the fraction to an animal feed to induce calcitriol synthesis in an animal when said animal is fed a normal amount of said animal feed. Therefore, claims 27-29 should be found novel and nonobvious.

New claim 30 is drawn to a method of inducing calcitriol synthesis in a pig or poultry by administering a food supplemented with a compound selected from the group consisting of isoflavones, lignans, coumestrol, resorcylic acid lactones and mixtures thereof to a pig or a poultry and inducing calcitriol synthesis in said pig or poultry. Glabe *et al.* and Goff *et al.*, neither individually, nor in combination with one another, teach or suggest supplementing a food with a compound of the claim and inducing calcitriol synthesis in a pig or poultry. Therefore, claims 27-29 should be found novel and nonobvious.

Therefore, the applicants respectfully submit that claims 1-11, 13-16, 18 and 22-30 are not inherently anticipated or made obvious by Glabe *et al.* or Goff *et al.* Reconsideration and withdrawal of the objection is respectfully requested.

CONCLUSION

Should questions remain after entry of the amendments and consideration of the remarks, the Office is kindly requested to contact the applicant's representative at the number provided herein.

Respectfully submitted,

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